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Damon H. DeHart

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TROY, MI 48084

EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

10/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/767,867	Applicant(s) DEHART, DAMON H.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,32-41,54,55,59,60,63,65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 32-41,54,55,59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,63,65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action will replace the Office action mailed out on 9/04/09.
2. This Office action is in response to the RCE filed on 6/22/09.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/09 has been entered.

Response to Amendment

4. According to the amendment, claims 64 and 67-69 have been canceled and claims 1-3, 63 and 66 have been amended. Accordingly, claims 1-10, 32-41, 54, 55, 59, 60, 63, 65 and 66 are pending in this present application and claims 1-10, 63, 65 and 66 are presented for examination.

Response to Arguments

5. With respect to Applicant's arguments that Humphrey fails to disclose the new limitation of "wherein the seamless member is sufficiently rigid to penetrate skin

without augmentation”, the arguments have been fully considered and they are persuasive, therefore, the rejection is hereby withdrawn. However, upon further search and consideration, claims 1-10, 63, 65 and 66 are rejected in view of new ground of rejection.

6. With respect to the argument that Boothroyd is non-analogous art even in light of KSR, they have been fully considered but they are moot in view of new ground of rejection.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).
Correction of the following is required: the specification fails to provide antecedent basis for the new limitation of “wherein the seamless member is sufficiently rigid to penetrate skin without augmentation”.

Claim Objections

8. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 5 recites the limitation of “the unitary member includes a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane”. Noting that the limitations of

“axis” and “plane” aforementioned above are imaginary features. There is no three dimensional object being claimed in claim 5.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New limitation “wherein the seamless member is sufficiently rigid to penetrate skin without augmentation”, especially the limitation of “without augmentation” is new matter. Appropriate correction is required.
11. Claim 2 is rejected for the same reason as claim 1 by the virtue of dependency on claim 1.
12. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was

filed, had possession of the claimed invention. New limitation “wherein the outerwall has sufficient rigidity to draw fluid from a patient without augmentation”, especially the limitation of “to draw fluid from a patient without augmentation” is new matter. Appropriate correction is required.

13. Claims 65 and 66 are rejected for the same reason as claim 63 by the virtue of dependency on claim 63.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 5 recites the limitation of “the unitary member includes a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane”. Noting that the limitations of “axis” and “plane” aforementioned above are imaginary features which being used to define a three dimensional object, no three dimensional object or feature is being claimed in claim 5, thereby rendering the scope of the claim unascertainable. For examination purpose, Examiner contends that any three dimensional object shall have multiple imaginary axis and planes, thus, a three dimensional object shall including at least a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane.
16. Claims 6-10 are rejected for the same reason as claim 5 by virtue of dependency on claim 5.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. **Claims 1, 2, 63, 65 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al. (U.S. 6,702,790).**
19. Referring to **claims 1 and 2**, Ross discloses (Figs. 3, 4, 5A-5D and 6A-6D) a hypodermic hollow cylindrical needle 30, 20, which includes a first end and a second end, wherein the second end attached to a syringe (Figs. 3 and 4), that is capable to use as a lancet device, comprising: a seamless member 30, 20 which is hollowed along at least a portion of its length wherein the needle including first and second ends wherein the first end further includes a first and second sharpened tips (Fig. 5B, near reference number 34 and Fig. 6B near reference number 24) (col. 3, lines 29-60). With respect to the limitation that the holder is configured to move the lancet to penetrate the skin of a patient, noting that the syringe and needle, is held and moved by a healthcare provider or a user to penetrate a patient skin, thus, Ross discloses the hypodermic needle is configured to move to penetrate the skin of a patient.

20. Referring to **claims 63, 65 and 66**, Ross discloses (Figs. 3, 4, 5A-5D and 6A-6D) a hypodermic hollow cylindrical needle 30, 20, which includes a first end and a second end, wherein the second end attached to a syringe (Figs. 3 and 4), that is capable to use as a lancet device and to withdrawn fluid from a patient without augmentation, comprising: a seamless member 30, 20 which is hollowed along at least a portion of its length wherein the needle including first and second ends wherein the first end further includes a first and second sharpened tips (Fig. 5B, near reference number 34 and Fig. 6B near reference number 24) (col. 3, lines 29-60). Figure 5B shows the tip of needle 30 includes a first surface and a second surface forming at an intersection to form a first tip and a second tip at the first end and the first tip and the second tip are separated by a first and second ground surface.

With the limitation of “a first ground surface and a second ground surface forming at an intersection” in **claim 63**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

Ross discloses using grinding process to produce tip geometry as shown in Figure 14B. It would have been obvious to use grinding process to produce the tip geometry as shown in Figure 5B.

With respect to the limitation of the first tip and the second tip are separated by first and second ground surface in **claim 65**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Figure 5B of Ross' drawing shows the tips are separated by two separated surface, Examiner contends that in the art of needle making using grinding to make tip geometry is old and well known in the art. Ross discloses using grinding process to produce tip geometry as shown in Figure 14B. It would have been obvious to use grinding process to produce the tip geometry as shown in Figure 5B.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. **Claims 1-10, 63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres (U.S. 3,906,932) in view of Humphrey (U.S. 5,607,401).**

24. Referring to **claims 1, 2, 63, 65 and 66**, Ayres discloses (see Figs. 1, 3, 5 and 7) a hollow cylindrical needle 10 and holder 22 (Fig. 5), that is capable to use as a lancet device, comprising: a seamless unitary member which is hollowed along at least a portion of its length wherein the needle including first for penetration of a patient skin and second ends for puncturing the rubber septum of a collection tube 22 (Background of The Invention) or holder, wherein the first end further includes a first and second sharpened tips 16, 18 (see col. 2, lines 18-65). With respect to the

limitation that the lancet holder is configured to move the lancet to penetrate the skin of a patient, noting that the Vacutainer tube 22 (Background of The Invention and Fig. 5), which also includes the needle, is held and moved by a healthcare provider or a user to penetrate a patient skin to withdraw blood sample (Background of the invention), thus, the needle is moved by Vacutainer tube 22 or holder 22. Thus, Ayres inherently discloses the holder 22 is configured to move the needle to penetrate the skin of a patient. Ayres fails to explicitly disclose the both ends needle of the needle 40 having the same needle point design as shown in Figure 1.

25. Still referring to **claims 1, 2, 63, 65 and 66**, noting that Ayres discloses the needle 40 is a double ended needle (Background of The Invention), one end for penetration of a septum of a Vacutainer and the opposite end for penetration of a blood vessel and the tip geometry is cut by grinding process. However, Humphrey discloses tip of a hypodermic needle can be oblique (Fig. 11 and col. 10, lines 46-50) and compound angles, which includes two sharpened tips (Fig. 12 and col. 10, lines 46-50) and the tip geometries are cut by grinding (col. 10, lines 49-51). It would have been obvious to one of ordinary skill in the art to provide tip geometry as disclosed in Figure 12 of Humphrey's drawing on first end of the needle 40, as disclosed by Ayres because it has been held that substitution of one known element for another to obtain predictable results is old and well known in the art. Further, noting that the tip geometry as shown in Figure 12 of Humphrey's drawing is similar with the tip geometry as shown in Figure1 of Ayres' drawing, thus, the

grinding process that being used to produce the tip geometry on the second end of needle 40 as disclosed by Ayres can be used to produce the tip geometry as disclosed in Figure 12 of Humphrey's drawing, therefore, it would have been obvious to one of ordinary skill in the art to provide the same tip geometry on both ends of needle 40 of Ayres in order to gain the advantage of using the same grinding process, thereby, reduce the manufacturing cost.

With respect to the limitation of "the outer wall defines a first and second ground surfaces" in **claims 63, 65 and 66**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

With respect to the limitation of the first tip and the second tip are separated by first and second ground surface in **claim 65**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not

governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Figure 5B of Ross' drawing shows the tips are separated by two separated surface, Examiner contends that in the art of needle making using grinding to make tip geometry is old and well known in the art. Ross discloses using grinding process to produce tip geometry as shown in Figure 14B. It would have been obvious to use grinding process to produce the tip geometry as shown in Figure 5B.

26. Referring to **claims 3, 4 and 5**, as already established in the rejection of claim 1 above, Ayres as modified by Humphrey discloses the invention substantially as claimed except for the specifically disclose the needle is made from stainless steel. However, stainless less steel is old and well known in the art for exhibiting excellent mechanical strength, biocompatibility and super corrosion resistant. It would have been obvious to one of ordinary skill in the art to make the needle of Ayres/Humphrey from stainless steel material so that it too would have the same advantage. Further, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the needle of Ayres/Humphrey made from stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With respect to the limitation of “a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane”, Examiner contends that the needle of Ayres or Humphrey of Ayes/Humphrey is three dimensional object and any three dimensional object shall have multiple imaginary axis and planes, thus, a three dimensional object shall including at least a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane.

27. Referring to **claims 6-10**, Ayres discloses (Fig. 7) the first ground surface 12 and second ground surface 14 is a single angle ground surface and each of the ground surface extends from the horizontal plane at an acute angle relative to the longitudinal axis. Figures 3 and 7 show the first and second ground surfaces 12, 14 mirror one another about the horizontal plane and each ground surface extends approximately 180 degrees about the longitudinal axis.
28. With respect to the limitation of “first and second ground surfaces which at least partially define first and second sharpened tips” in claims 3-10, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the

product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Tuan V Nguyen/
Examiner, Art Unit 3731